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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,316	09/25/2001	Toshio Imai	TOYAM77.001AUS	1352

7590 06/13/2005

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/963,316	IMAI ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-8,12-15 and 17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are currently pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 4, 2005 has been entered.

Election/Restrictions

1. **Claims 1-8 and 12-14 stand withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the Paper filed December 1, 2003.

Claims 15 and 17-20 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the Paper filed December 1, 2003.

Accordingly, **claims 9-11 and 16 are the subject of examination** in the present Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 9-11 and 16 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 6,013,257 to Pan et al (A on form PTO-892; of record) as evidenced by Hoover et al. (J. Biol. Chem. [2000] 275(30):23187-23193; U on form PTO-892; of record).

The claims are drawn to the treatment of an autoimmune disease, specifically multiple sclerosis, using an antibody specific for the CX3C chemokine "fractalkine." It is noted that the protein named

herein as "fractalkine" is also commonly known in the art as "neurotactin," as evidenced by Hoover (Abstract in particular). The '257 patent teaches the making and use (column 16, line 62 through column 17, line 59; column 5, line 64 through column 6, line 18; column 7, lines 1-4 and claim 4 in particular) of monoclonal antibodies to the full length of fractalkine as well as to fragments thereof. The '257 patent teaches and claims the treatment of multiple sclerosis in a patient with antibodies to human neurotactin, the sequence of which is disclosed in the '257 patent as SEQ ID NO: 4 (column 2, lines 21-31; column 34, line 16 through column 35, line 14 and claims 1-4 in particular). Example 7 of the '257 patent (column 34, lines 16-59) exemplifies the use of antibodies raised to the full extra-cellular domain of fractalkine for the inhibition of an animal model of multiple sclerosis (EAE). Furthermore, the '257 patent specifically recites the preferred use of monoclonal antibodies (column 7, lines 1-4 in particular) that do not cross-react with other proteins naturally in the presence of fractalkine (column 6, lines 5-9 in particular). The '257 patent teaches that antibodies to fractalkine are included within the scope of fractalkine antagonists (column 6, lines 11-14 in particular) and therapeutic use of anti-fractalkine antibodies as fractalkine inhibitors (column 7, lines 13-17 in particular) and that inflammation associated with multiple sclerosis can be treated with inhibitors of fractalkine function (column 34, line 60 through column 35, line 14 in particular). Interaction of fractalkine with CX3CR1 is a function of fractalkine and is therefore encompassed by the teachings of the '257 patent. The prior art teaching clearly anticipates the claimed invention.

Applicant's arguments and the declaration of inventor Toshio Imai filed April 4, 2005 have been fully considered but they are not persuasive.

The Imai declaration demonstrated the production of monoclonal antibodies specific for the CX3C chemokine fractalkine (neurotactin) by the methods described in Applicant's own application. The declaration discloses that 9 out of 15 monoclonal antibodies thus produced did not inhibit the binding of fractalkine to CX3CR1-expressing cells. Applicant asserts in the response to the rejection, on the basis of this declaration, that the '257 patent cannot be considered anticipatory because not all antibodies raised to fractalkine are inhibitory of the interaction between fractalkine and C3XCR1. Applicant's arguments are not tenable. Like the method of the '257 patent, the monoclonal antibodies of the Imai declaration were raised against the full-length fractalkine protein. The Imai declaration demonstrates that 40% of antibodies raised to full-length fractalkine by a method conventional in the art were capable of inhibiting fractalkine interaction with C3XCR1. The Imai declaration has shown no particular feature of the immunization methods of Applicant, as compared to the immunization methods of the '257 patent, that would favor the production of inhibitory antibodies. Accordingly, based upon the evidence provided by

the Imai declaration, about 40% of the neurotactin-specific antibodies of the '257 patent would have inhibited the binding of fractalkine to CX3CR1.

Conclusion

3. No claim is allowed.

4. This is a continued examination of applicant's earlier Application No. 09/963,316. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 7, 2005

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644